K122647

SYNTHES®

5 510(k) Summary

FEB 2 8 2013

Date Prepared	February 15, 2013
Submitter	Synthes (USA) 1301 Goshen Parkway West Chester, PA 19380 United States of America
Contact	Alan T. Haley haley.alan@synthes.com (484) 356-9763
Device Name	Synthes Patient Specific Plates
Classification Name	Class II
Regulation:	21 CFR 872.4760
Product Code	JEY
Common Name:	Bone Plate

Predicate Devices

- Synthes MatrixMANDIBLE Plating System (K063790)
- Synthes MatrixMANDIBLE Preformed Reconstruction Plates (K091144)

Indications for Use

Synthes Patient Specific Plates are intended for use in oral and maxillofacial surgery, trauma and reconstructive surgery.

Specific Indications for Use:

- Primary mandibular reconstruction with bone graft
- Temporary bridging until delayed secondary reconstruction
- Secondary mandibular reconstruction
- Comminuted mandibular fractures
- Fractures of edentulous and/or atrophic mandibles
- Unstable mandibular fractures
- Maxillary reconstruction with or without bone graft
- Maxillary trauma

Device Description

Synthes Patient Specific Plates are a metallic bone plates used in conjunction with metallic bone screws for the internal fixation of maxillofacial bone, specifically in the areas of the mandible and maxilla. The design and dimensions (number and placement of holes, hole angulation, plate length, etc.) of each plate are based on of the patient's anatomic (CT scan) data, the surgical plan, and input from the surgeon. Synthes Patient Specific Plates are not intended to be further bent or contoured during surgery. Synthes Patient Specific Plates are manufactured from commercially pure titanium, are provided non-sterile, must be sterilized prior to use, and are intended for single use only.

Comparison to Predicate Devices

Indications

The Indications statement for the proposed device and both predicate devices includes use in oral and maxillofacial surgery, trauma, and reconstructive surgery. Both the proposed device and predicate Synthes MatrixMANDIBLE Preformed Reconstruction Plate list specific Indications for Use in addition to the more general intended use statement. All of the specific Indications for the proposed device are within the scope of the general use of the device.

The differences in the Indications statement for the proposed device in comparison to the predicates do not constitute a new intended use.

Technological Similarities

- The proposed device and the predicate devices share the same fundamental principle of operation - metallic plates used in conjunction with metallic screws for oral and maxillofacial surgery, trauma, and reconstructive surgery.
- The proposed device and the predicate devices are manufactured from commercially pure titanium, which meets the requirements of ASTM standard F67. Titanium has a long, established history of use as a surgical implant material.
- The proposed device is offered in thicknesses of 2.0 mm and 2.5 mm. The thicknesses of the predicate devices range from 2.0 mm to 2.8 mm.
- The proposed device and both predicate devices feature the same screw hole geometry and are compatible with all previously cleared MatrixMANDIBLE bone screws.
- The proposed device and both predicate devices can be cut intraoperatively.
- The proposed plate and both predicates are compatible with the Synthes Condylar Head Add-on-System (K081747).
- The proposed device has a constant thickness along the entirety of the plate length. The body section of the predicate MatrixMANDIBLE Preformed Reconstruction plates has a similar constant thickness.

Technological Differences

- The angles and dimensions of each Synthes Patient Specific Plate are determined based on the patient anatomy and surgical plan and should not be further contoured intraoperatively. The predicate Synthes MatrixMANDIBLE Reconstruction plate is flat and is intended to be contoured intraoperatively to the required shape. The ramus and symphysis sections of the predicate Synthes MatrixMANDIBLE Preformed Reconstruction Plate are intended to be intraoperatively contoured to the required shape.
- The proposed device has a constant thickness along the entirety of the plate length. The predicate Synthes MatrixMANDIBLE Reconstruction Plates and the ramus and symphysis sections of the predicate Synthes MatrixMANDIBLE Preformed Reconstruction plates have bending notches and resulting variations.

Non-clinical performance data

Bench testing was used to demonstrate that any differences, where they do exist, do not negatively impact safety and effectiveness.

A cross-sectional analysis compared the in-plane and out-of-plane resistance to bending of the proposed and predicate devices. The bending resistance of the proposed plates was determined to be equivalent or better to the predicate devices. Therefore, it is concluded that the proposed plates do not raise any new questions of safety or efficacy in terms of bending resistance.

Mechanical testing compared the cantilever bend fatigue life of the proposed and predicate devices. The fatigue life of the proposed plates was determined to be equivalent or better to the predicate devices. Therefore, it is concluded that the proposed plates do not raise any new questions of safety or efficacy in terms of cantilever bend fatigue life.

Clinical performance data

Clinical testing was not necessary for the determination of substantial equivalence.

Substantial Equivalence

The proposed device has the same intended use as the predicate devices. The bench testing included in this submission demonstrates that the differences in technological characteristics do not raise any new questions of safety and effectiveness. The information submitted supports substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 28, 2013

Mr. Alan Haley
Regulatory Affairs Specialist
Synthes, Incorporated
1301 Goshen Parkway
WEST CHESTER PA 19380

Re: K122647
Trade/Device Name: Synthes Patient Specific Plates
Regulation Number: 21 CFR 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: February 15, 2013
Received: February 19, 2013

Dear Mr. Haley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kwame O. Ulmer for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SYNTHES®

4 Indications for Use Statement

510(k) Number (if known): K122647

Device Name:

Synthes Patient Specific Plates

Indications for Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner -S
2013.02.28
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Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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